Complete Summary

GUIDELINE TITLE

Round spermatid nucleus injection (ROSNI).

BIBLIOGRAPHIC SOURCE(S)

Round spermatid nucleus injection (ROSNI). Fertil Steril 2003 Sep; 80(3):687-9. [29 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

IDENTIFYING INFORMATION AND AVAILABILITY

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Male infertility

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Medical Genetics
Obstetrics and Gynecology
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations for the treatment of male infertility using round spermatid nucleus injection (ROSNI)

TARGET POPULATION

Men who are infertile

INTERVENTIONS AND PRACTICES CONSIDERED

Round spermatid nucleus injection (ROSNI)

MAJOR OUTCOMES CONSIDERED

- Fertilization rates
- Adverse effects of procedure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This bulletin was approved by the Practice Committee of the American Society for Reproductive Medicine and the Board of Directors of the American Society of Reproductive Medicine.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Round spermatid nucleus injection (ROSNI) is a method of assisted fertilization in which precursors of mature spermatozoa are injected into oocytes.
- ROSNI should not be performed when more mature sperm forms (elongating spermatids or spermatozoa) can be identified and used for intracytoplasmic sperm injection (ICSI).
- Patients who may be candidates for ROSNI should receive careful and thorough pretreatment counseling to ensure they are clearly informed of the limitations and potential risks of the procedure.
- Application of ROSNI in clinical human in vitro fertilization (IVF) should be considered experimental and therefore requires approval and oversight by an appropriately constituted Institutional Review Board.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective treatment of male infertility using round spermatid nucleus injection (ROSNI)

POTENTIAL HARMS

Offspring conceived via in vitro fertilization (IVF) with round spermatid nucleus injection (ROSNI) may be at risk for infertility or even more severe genetic defects.

QUALIFYING STATEMENTS

QUALLEYING STATEMENTS

- While this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources and institutional or clinical practice limitations.
- The Practice Committee recommends that round spermatid nucleus injection (RSNI) be considered an experimental procedure that should be applied only in the setting of a clinical trial approved and overseen by a properly constituted Institutional Review Board.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Round spermatid nucleus injection (ROSNI). Fertil Steril 2003 Sep; 80(3):687-9. [29 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Sep

GUI DELI NE DEVELOPER(S)

American Society for Reproductive Medicine - Private Nonprofit Organization

SOURCE(S) OF FUNDING

American Society for Reproductive Medicine

GUIDELINE COMMITTEE

Practice Committee of the American Society for Reproductive Medicine

Practice Committee of the Society for Assisted Reproductive Technology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Society for Reproductive Medicine</u> Web site.

Print copies: Available from American Society for Reproductive Medicine, 1209 Montgomery Highway, Birmingham, Alabama 35216-2809; Phone: (205) 978-5000; Fax: (205) 978-5005; E-mail: asrm@asrm.org; Web site: www.asrm.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 23, 2004.

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